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(54) CONTROLLED OXYGEN/ANTI-MICROBIAL RELEASE FILMS

KONTROLIERTE SAUERSTOFF/ANTIMIKROBIELLE TRENNFILME

PELICULES DE LIBERATION CONTROLEE D'OXYGENE/AGENT MICROBICIDE

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Description**Background of the Invention**

5 **[0001]** The present invention relates to the microbial decontamination arts. It finds particular application with bandages and wipes and will be described with particular reference thereto. It is to be appreciated, however, that the present invention will also find application in other areas where oxidants, anti-microbial agents, or medicaments are generated *in situ* such as in gloves, drapes, and the like.

10 **[0002]** Heretofore, various wipes and other cloth-like materials have been impregnated with an anti-microbial agent. The anti-microbial agent, most often in a liquid form, is coated on, caused to soak into, or otherwise attached to a flexible carrier or film. Often, the anti-microbial agent treated film is packaged in a sealed pouch to prevent evaporation or contamination. The pouch is opened to use the wipe. The wipe is typically packaged with a sufficient amount of a liquid carrier that a wet layer of carrier and anti-microbial agent are left on the wiped surface. Alternately, the carrier or a solvent such as water may be added to the film when the package is opened to render the anti-microbial agent more mobile.

15 **[0003]** Flexible fabric or fiber-like materials which are apt to support mildew, mold, or bacterial growth are often treated with an anti-microbial agent. Often, the fabric or fiber carries materials, e.g., sizing which are apt to support such microbial growth. The anti-microbial agent is typically intermixed with the material which is apt to support microbial growth.

20 **[0004]** One of the problems with wipes and films of this type is that the anti-microbial agent requires a long shelf life. The wipe may be in the package for weeks or months before it is opened. After the wipe is used and discarded, a significant amount of the anti-microbial agent remains in the wipe. If the anti-microbial agent is a toxin or poison with a long life, disposal of the used wipe carries undesirable environmental and ecological side effects.

25 **[0005]** The present invention contemplates a new and improved material which overcomes the above-referenced problems and others.

Summary of the Invention

30 **[0006]** In accordance with one aspect of the present invention, an arrangement of components carries two or more constituents which in the presence of a solvent form oxygen or a strong oxidant. In some of the preferred embodiments of the invention the arrangement of components is in the form of a film.

35 **[0007]** In accordance with the present invention, the arrangement carries at least two reagents that react in the solvent to form the oxygen or anti-microbial agent. A means is provided to maintain the constituents or reagents separated until contacted with a solvent.

40 **[0008]** The means for keeping the two constituents separated consists of a filter.

45 **[0009]** In accordance with another aspect of the present invention, means are provided for controlling a reaction rate between the constituents to control the rate at which the oxygen or anti-microbial agent is produced.

50 **[0010]** In accordance with a more limited aspect of the present invention, the means for controlling the reaction rate includes added buffers which increase the pH to accelerate the reaction rate or decrease the pH to retard the reaction rate.

55 **[0011]** In accordance with another aspect of the present invention, the first reagent includes an acetyl donor and the second reagent includes a perborate. Suitable acetyl donors include acetylsalicylic acid which react with a perborate, preferably sodium perborate monohydrate or sodium perborate anhydrous to form peracetic acid and salicylic acid. The peracetic acid is a strong oxidant which decomposes to liberate free oxygen. The salicylic acid is a keratotic. Other suitable acetyl donors include tetraacetyl ethylenediamine (TAED), diacetyl dioxohexahydrazine (DADHT), tetraacetyl glycoluril, and sodium nanonoyl oxygenzene sulfonate.

60 **[0012]** In one method of use, the arrangement is formulated such that the constituents react quickly, i.e. have a very short half-life. The arrangement or the surface to be disinfected are wet, such as by spraying or dipping. The solvent allows the constituents to react, generating the anti-microbial agent or oxidant. Preferably, the half-life of the anti-microbial agent or oxidant is only a minute or two.

65 **[0013]** In accordance with another aspect of the present invention, the arrangement is incorporated in a bandage and configured such that the reaction progresses very slowly, i.e. there is a long half-life. The bandage is placed over a wound. Moisture from the wound acts as the solvent allowing the reaction which produces the anti-microbial agent and/or oxidant to take place. Preferably, the half-life is on the order of several hours to a day or two such that the anti-microbial agent or oxygen is produced substantially continuously over the time that the dressing is applied to the wound.

70 **[0014]** One advantage of the present invention is that it has a relatively long shelf-life and a relatively short half-life.

75 **[0015]** Another advantage of the present invention is that the anti-microbial agent or oxidant is generated *in situ* at a controllable rate.

[0016] Another advantage of the present invention is that it effectively kills microbes yet is not polluting when discarded.

[0017] Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

5

Brief Description of the Drawings

[0018] The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

10 FIGURE 1 illustrates the present invention in which reagent particles are separated by a filter;

15 FIGURE 2 illustrates a wound dressing in accordance with the present invention;

FIGURE 3 illustrates another embodiment of the present invention which may advantageously be incorporated into the dressing of FIGURE 2;

FIGURE 4 illustrates a glove incorporating the present invention.

Detailed Description of the Preferred Embodiments

20 [0019] With reference to FIGURE 1, particles of the first reagent **12** and particles of the second reagent **14** are separated by a filter sheet **18**. The filter sheet has a pore size which is sufficiently small relative to the particle size of the two powdered reagents that the particles are maintained physically separated. Yet, once dissolved in the solvent, the pore size is sufficiently large that the solvent and dissolved materials pass therethrough and react. A top or first outside coating layer **20** and a bottom or second outside coating layer **22** shield the particles of the two reagents from physical interaction so that they are not lost or brushed off before the film is actuated with the solvent. At least one of the two covering layers is permeable to the solvent to allow ready access to the constituents.

25 [0020] When used as a wipe, the arrangement may be dipped or sprayed with water to activate it. Alternately, the surface to be disinfected may be wet such that the arrangement and the impregnated reagents become wet, dissolve, and react from the water on the surface. When used as a bandage, the arrangement may be initially dampened, such as with spray, to start the reaction. The reaction may be continued or in some embodiments initiated by moisture from the wound. When used as a dressing, the oxidant disinfectant agent not only functions as an anti-microbial agent to prevent infection, but also liberates free oxygen which promotes healing.

30 [0021] In one preferred embodiment, one of the reagents **12** includes a sodium or other perborate in dry form or other dry constituents which liberate oxygen. Sodium perborate monohydrate and sodium perborate anhydrous are preferred. The other reagent **14** includes a dry acid precursor. The dry acid precursor and the dry persalt react when dissolved in water or other appropriate solvent to form a strong oxidant. Further to the preferred embodiment, the acid precursor is an acetyl donor, such as acetylsalicylic acid, tetraacetyl ethylenediamine (TAED), diacetyl dioxohexahydriazine (DADHT), tetraacetyl glycoluril, and sodium nanonoyl oxyenzene sulfonate. Acetylsalicylic acid and sodium perborate react in water to form peracetic acid, salicylic acid, and sodium metaborate. Peracetic acid is a strong oxidant with a relatively short half-life that liberates free oxygen as it breaks down. Salicylic acid is a topical keratotic which softens or dissolves horny layers of the epidermis such as warts, callouses, and dead skin. In addition to softening skin, salicylic acid has anti-microbial properties.

35 [0022] It is also advantageous to control the reaction rate such that the rate at which the anti-microbial agent or oxygen is produced occurs substantially at a preselected rate. In the embodiment of FIGURE 1, a means for controlling the reaction includes the pore size of the filter material **18**. In one embodiment, the reaction rate is controlled by limiting communication between the constituents. The means for controlling the reaction rate further includes the permeability of the covering layers **20** and **22**. By limiting the rate at which the solvent can reach the dry constituents, the rate at which there is sufficient solvent to allow them to react is controllable. In another embodiment, the means for controlling the reaction rate includes the addition of further powdered reagents. In particular, the reaction between the preferred acetylsalicylic acid and sodium perborate is pH sensitive. At a high pH, the reaction occurs quickly. When the pH is buffered such that it remains near neutral even when the peracetic acid is produced, the reaction proceeds more slowly. The peracetic acid buffered nearer neutral remains stable for a relatively long duration, generally on the order of hours, rather than breaking down into oxygen quickly as it does when the pH is high. Lower pH serves as a stabilizer. Analogously, temperature affects the reaction. The maximum yields of peracetic acid are higher at 20° C while the times needed to reach the maximum are longer at lower temperature. The time for converting TAED to peracetic acid is longer than for DADHT.

40 [0023] With reference to FIGURE 2, a wound dressing **30** includes a section of the arrangement **10** disposed between a gauze or other porous wound contacting layer **32** and a covering layer **34**. Preferably, the covering layer **34** includes

an adhesive layer **36** which adheres to the arrangement **10** to a central portion thereof, adheres the wound contacting portion **32**, and adheres to the patient's skin around the wound. The arrangement **10** has the construction set forth in FIGURE 1 or in those described below. In one preferred embodiment, the film **10** has substantially the construction of FIGURE 1. The lower layer **22** disposed towards the patient's skin is porous to moisture exiting the wound. Lower layers of different porosity are used for different types of wounds. For example, the bandage is advantageously used to generate oxygen to promote the healing of a wound. The lower layer **22** has a porosity which permits water vapor to pass therethrough at a controlled rate. The water vapor causes a limited wetting of the dry reagents such that they dissolve gradually and react, at an analogous controlled rate. Preferably, the powdered constituents are buffered to have a relatively high pH such that the preferred acetylsalicylic acid and perborate form a peracetic acid with such a high pH that it is relatively unstable and breaks down quickly to free oxygen. A pH of 11 or higher is preferred for a quick breakdown to oxygen. The porosity of the lower layer **22** is again permeable to the free oxygen such that it enters the wound. The upper layer **20**, being redundant with the layer **34** may be eliminated. The layer **34**, and layer **20** if redundantly applied, may be moisture and gas permeable or may be semipermeable to either moisture or gas. Venting allows excess water vapor to escape. In some applications, layer **34** is impermeable.

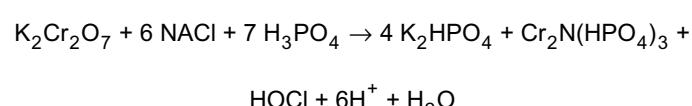
[0024] For other types of wounds, the generation of a strong anti-microbial agent is important as well as the production of oxygen. The porosity of lower layer **22** is again selected to control the amount of moisture permitted to enter. If the dressing is to be applied for a relatively short duration, e.g. a few hours, the lower layer **22** is preferably permeable by liquids such as water vapor from the skin, liquids exiting the wounds, or water sprayed from a spray bottle to actuate the dressing.

[0025] The preferred acetylsalicylic acid and perborate react to form not only peracetic acid, but also salicylic acid. Preferably, the lower layer **22** is sufficiently porous that it allows the dilutant with dissolved salicylic acid to flow back into the wound to promote healing. As another alternative, the salicylic acid can be used to remove horny layers of the epidermis. The film may be wet, such as by spraying or dipping and then applied to the area to be treated. Preferably, the dry constituents include a gel which holds the water and continues the reaction and permits the salicylic acid solution to continue to reach the horny layer for several hours to a day. For relatively longer stability, an after reaction pH of 9.2-10 is preferred. The dry reagents **12** and **14** may also include emollients and other skin softeners.

[0026] With reference to FIGURE 3, the constituents **12** and **14** are carried by layers of woven, non-woven, or knitted fibers or open cell or foam **40**, **42**. The dry constituents are sprayed and dried, impregnated, dry sprayed, or otherwise attached to or incorporated into the fibers or foam layers. A filter layer **18** holds the dry particulates apart. Outer layers **20** and **22** contain and protect layers **40** and **42**. At least one of the outer layers is fluid permeable such that the solvent can penetrate, dissolve the dry constituents, and start the chemical reaction. The porosity of the filter **18** and the outer layers **20**, **22** control the rate at which the dilutant can enter and the reagents intermix, hence the rate of reaction. Additional buffering compositions may also control the rate of reaction. Surfactants, detergents, emollients, and the like may also be included in dry form.

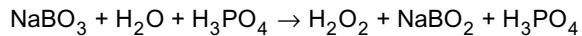
[0027] With reference to FIGURE 4, the constructions of the preceding embodiments can be fabricated into various articles. For example, a protective glove **50** is defined by a continuous impermeable hand-shaped layer **52** of rubber, plastic, or other film material which is impermeable to the dilutant, the anti-microbial agent, strong oxidants, and gaseous oxygen, as well as any emollients, detergents, or other substances which may be dissolved in the solvent. The arrangement **10** is adhered to the outer surface of all or selected portions of the glove. The arrangement **10** is preferably laminated over the palm, thumb, and finger pad portions of the glove, i.e. the portions of the glove which would contact a grasped or touched object. An outer, permeable layer **22** surrounds the film **10** protecting it. Preferably, the outer layer **22** is a material which can be readily affixed to the impermeable liner **52**, such as by heat fusion, adhesives, or the like. Preferably, the film **10** has periodic discontinuities where the inner and outer layers contact and adhere to each other.

[0028] Although the preferred embodiment uses an acetylsalicylic acid and sodium perborate reaction, other oxidizing or antimicrobial agents can also be generated *in situ*, such as chlorine dioxide, chlorine, hydrogen peroxide, and mixtures thereof. More specifically, potassium chromates, sodium chloride, and phosphates may be mixed according to the following equation to produce a strong chlorine oxidant on the addition of water:



55 Optionally, excess dichromate and an organic corrosion inhibitor may be provided for improved buffering and corrosion inhibiting.

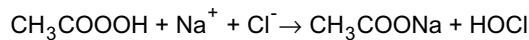
[0029] Hydrogen peroxide and an inorganic inhibitor can be generated:



5 [0030] Similarly, chlorine dioxide can be generated from powdered ingredients on the addition of water:



10 [0031] A mixed biocide system can be achieved by adding sodium chloride to the peracetic acid reaction to produce hypochlorous acid. Because sodium chloride is a component of physiological fluids, the reaction can be partially physiologically regulated.



15 Excess peracetic acid is deliberately present such that both peracetic acid and hypochlorous acid are present in the biocidal solution.

[0032] Other reagents include perborates which react in water to liberate free oxygen, and constituents which react to form other medically useful compositions.

20 [0033] The invention has been described with reference to the preferred embodiment. Obviously, modifications and alterations will occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

25 Claims

1. An arrangement of components (10) including arrangement of component layers (20, 22) which contains dry constituents that react to generate at least one of oxygen and a strong oxidant in the presence of a solvent
 30 wherein the dry constituents include a first dry reagent (12) in particulate form and a second dry reagent (14) in particulate form, particles of the first and second reagents being contained in between the layers (20, 22), the first and second reagent particles dissolve in the solvent and react with each other *in situ* to generate the at least one of oxygen and the strong oxidant; and **characterized by**:

35 a sheet of filter material (18) which pores are smaller than the first and second reagent particles, said sheet separating the first and second reagent particles such that the particles of the first reagent and the particles of the second reagent are maintained physically separated from each other and thereby unable to react with each other until dissolved by the solvent.

40 2. The arrangement of components as set forth in preceding Claim 1 further **characterized by** the first reagent including an acid precursor and the second reagent including a perborate, the acid precursor and perborate reacting in the presence of water to generate the strong oxidant and further including at least one of:

45 a surfactant;
 a detergent;
 an emollient;
 a pH buffer; and
 a water absorbing gel.

50 3. The arrangement of components as set forth in either of preceding claims 1 and 2, further **characterized by** the first reagent including an acetyl donor and the second reagent including a perborate such that peracetic acid is generated.

55 4. The arrangement of components as set forth in claim 3 further **characterized by** the acetyl donor including at least one of acetylsalicylic acid, tetraacetyl ethylenediamine, diacetyl dioxohexahydatriazine, tetraacetyl glycoluril, and sodium nanonoyl oxygenzene sulfonate.

5. The arrangement of components as set forth in any of preceding claims 1-4 further **characterized by** a means for

controlling a reaction rate between the first and second reagents.

6. The arrangement of components as set forth in claim 5 further **characterized by** the reaction rate controlling means controlling the reaction rate to cause a complete reaction in less than 5 minutes, whereby the strong oxidant is generated rapidly enabling the arrangement to be used as an anti-microbial wipe.

7. The arrangement of components as set forth in any one of the preceding claims further **characterized by** the filter including at least one of:

10 woven fibers;
non-woven fibers;
knitted fibers;
a permeable synthetic sheet; and
a flexible foam layer.

15 8. The arrangement of components as set forth in any one of the preceding claims further **characterized by** the arrangement being affixed to an exterior of a dilutant-impermeable glove.

20 **Patentansprüche**

1. Anordnung von Bestandteilen (10) enthaltend eine Anordnung von Bestandteilschichten (20, 22), welche trockene Anteile enthält, welche reagieren, um mindestens Sauerstoff und/oder einen starken Oxidanten in der Gegenwart eines Lösungsmittels zu erzeugen, wobei die trockenen Anteile ein erstes Trockenreagenz (12) in Partikelform und ein zweites Trockenreagenz (14) in Partikelform enthalten, wobei Partikel des ersten und zweiten Reagenz zwischen den Schichten (20, 22) enthalten sind, die ersten und zweiten Reagenzpartikel sich in dem Lösungsmittel auflösen und *in situ* miteinander reagieren, um mindestens den Sauerstoff und/oder den starken Oxidanten zu erzeugen; und **gekennzeichnet durch**:

30 ein Blatt Filtermaterials (18), dessen Poren kleiner sind als die ersten und zweiten Reagenzpartikel, welches Blatt die ersten und zweiten Reagenzpartikel so trennt, dass die Partikel des ersten Reagenz und die Partikel des zweiten Reagenz physikalisch voneinander getrennt gehalten werden und **dadurch** nicht in der Lage sind, miteinander zu reagieren, bis sie von dem Lösungsmittel aufgelöst werden.

35 2. Anordnung von Bestandteilen nach dem vorhergehenden Anspruch 1, weiterhin **dadurch gekennzeichnet, dass** das erste Reagenz einen Säurevorgänger und das zweite Reagenz ein Perborat enthält, wobei der Säurevorgänger und das Perborat in der Gegenwart von Wasser reagieren, um den starken Oxidanten zu erzeugen, und weiterhin mindestens einen der Stoffe

40 ein Tensid (Surfactant);
ein Detergens;
einen Weichmacher;
einen pH-Puffer; und
ein wasserabsorbierendes Gel

45 enthält.

50 3. Anordnung von Bestandteilen nach einem der vorhergehenden Ansprüche 1 und 2, weiterhin **dadurch gekennzeichnet, dass** das erste Reagenz einen Acetylspender und das zweite Reagenz ein Perborat enthält, so dass Peressigsäure erzeugt wird.

55 4. Anordnung von Bestandteilen nach Anspruch 3, weiterhin **dadurch gekennzeichnet, dass** der Acetylspender mindestens einen der Stoffe Acetylsalizylsäure, Tetraacetyl-Äthylendiamin, Diacetyl-Dioxohexahydrazin, Tetraacetyl-Glykouril und Natrium-Nanonoyl-Oxygenen-Sulfonat enthält.

5. Anordnung von Bestandteilen nach einem der vorhergehenden Ansprüche 1 - 4, weiterhin **gekennzeichnet durch** ein Mittel zum Steuern einer Reaktionszeit zwischen den ersten und zweiten Reagenzien.

6. Anordnung von Bestandteilen nach Anspruch 5, weiterhin **dadurch gekennzeichnet, dass** das Reaktionszeit-Steu-
ermittel die Reaktionszeit so steuert, dass eine vollständige Reaktion in weniger als 5 Minuten erfolgt, wodurch
der starke Oxidant schnell erzeugt wird und es ermöglicht, dass die Anordnung als anti-mikrobiischer Wischer
verwendet werden kann.

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7. Anordnung von Bestandteilen nach einem der vorhergehenden Ansprüche, weiterhin **dadurch gekennzeichnet,**
dass der Filter mindestens einen der folgenden Bestandteile enthält:

10 verwobene Fasern;
nicht-verwobene Fasern;
gestrickte Fasern;
ein durchlässiges synthetisches Blatt; und
eine flexible Schaumschicht.

15 8. Anordnung von Bestandteilen nach einem der vorhergehenden Ansprüche, weiterhin **dadurch gekennzeichnet,**
dass die Anordnung an einer Außenfläche eines für Verdünnungsmittel undurchlässigen Handschuhs befestigt ist.

Revendications

20 1. Disposition de composants (10) comprenant une disposition de couches (20, 22) de composants qui contient des
constituant secs qui réagissent pour générer au moins un élément parmi de l'oxygène et un oxydant puissant en
présence d'un solvant, selon lequel les constituants secs comprennent un premier réactif sec (12) sous forme de
particules et un deuxième réactif sec (14) sous forme de particules, des particules des premier et deuxième réactifs
étant contenues entre les couches (20, 22), les particules des premier et deuxième réactifs se dissolvent dans le
solvant et réagissent les unes avec les autres *in situ* pour générer au moins un élément parmi de l'oxygène et
l'oxydant puissant ; et **caractérisée par**

25 une feuille d'un matériau formant filtre (18) dont les pores sont inférieurs à la tailles des particules des premier
et deuxième réactifs, ladite feuille séparant les particules des premier et deuxième réactifs de telle sorte que les
particules du premier réactif et les particules du deuxième réactif sont maintenues séparées physiquement les
unes des autres et de ce fait, ne peuvent pas réagir les unes tant qu'elles n'ont pas été dissoutes par le diluant.

30 2. Disposition de composants selon la revendication 1, **caractérisée en outre en ce que** le premier réactif comprend
un précurseur acide et le deuxième réactif comprend un perborate, le précurseur acide et le perborate réagissant
en présence d'eau pour générer l'oxydant puissant, et comprenant en outre au moins un élément parmi :

35 un agent tensio-actif,
un détergent,
un émollient
40 un tampon de pH ; et
un gel d'absorption d'eau.

45 3. Disposition de composants selon l'une quelconque des revendications 1 et 2, **caractérisée en outre en ce que**
le premier réactif comprend un donneur d'acétyle et le deuxième réactif comprend un perborate de telle sorte qu'un
acide peracétique est généré.

50 4. Disposition de composants selon la revendication 3, **caractérisée, en outre, en ce que** le donneur d'acétyle
comprend au moins un élément parmi de l'acide acétylsalicylique, du tétra-acétyle éthylène-diamine, diacétyle
dioxohexahydatriazine, tétra-acétyle glycolurile, et du nanonyle oxygénè sulfonate de sodium.

55 5. Disposition de composants selon l'une quelconque des revendications précédentes 1 à 4, **caractérisée en outre**
par un moyen permettant d'agir sur le taux de réaction entre les premier et deuxième réactifs.

6. Disposition de composants selon la revendication 5, **caractérisée en outre en ce que** les moyens d'action sur le
taux de réaction permettent d'obtenir une réaction totale en moins de 5 minutes, selon lequel l'oxydant puissant
est généré rapidement ce qui permet d'utiliser cette disposition comme chiffon anti-microbien.

7. Disposition de composants selon l'une quelconque des revendications précédentes, **caractérisée en outre en**

ce que le filtre comprend au moins un élément parmi :

des fibres tissées
des fibres non tissées
des fibres tricotées
une feuille de synthèse perméable ; et
une couche de mousse souple.

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8. Disposition de composants selon l'une quelconque des revendications précédentes, caractérisée en outre en
10 ce que cette disposition est fixée à l'extérieur d'un gant imperméable au solvant.

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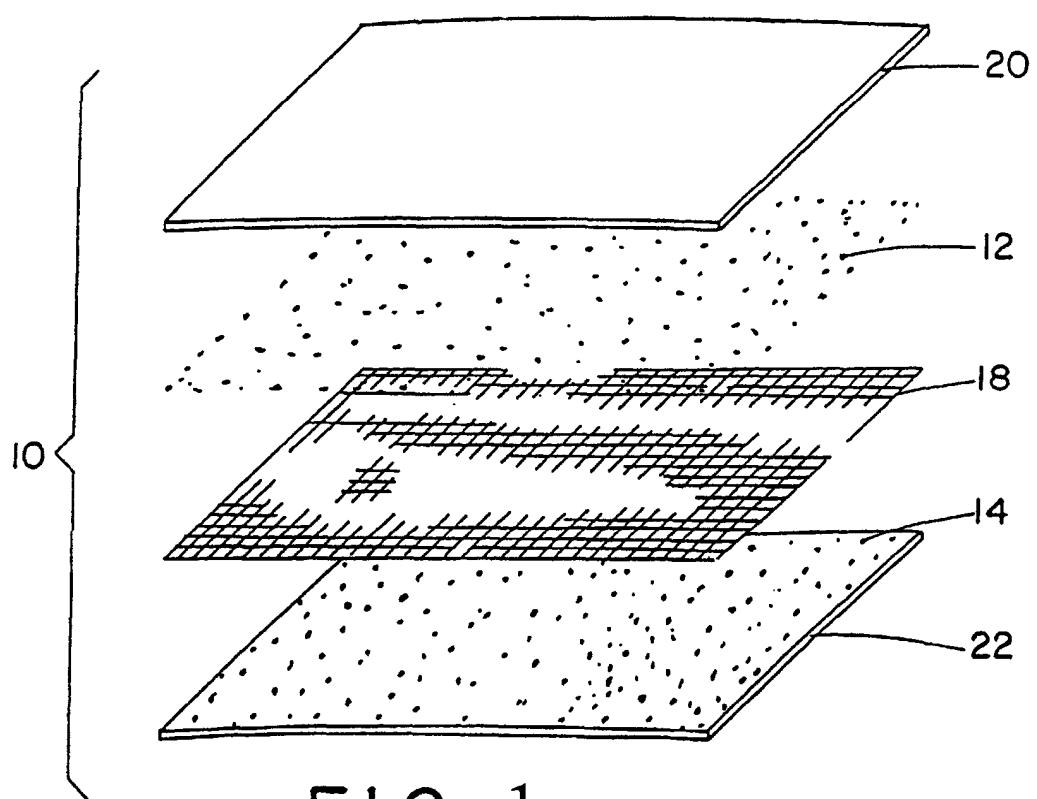


FIG. 1

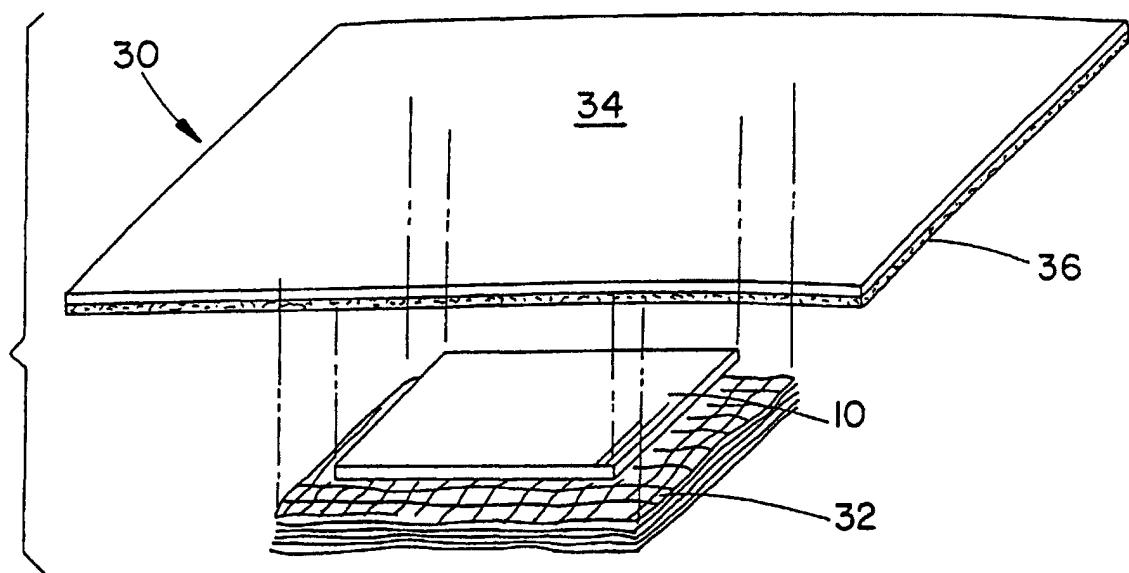


FIG. 2

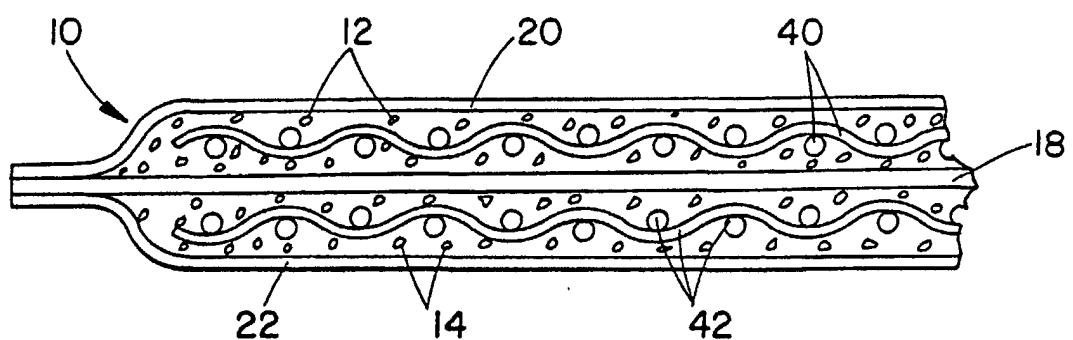


FIG. 3

